REMARKS

Claims 1-15 are currently pending; claims 16-22 have been withdrawn. No claims have been allowed.

Claims 1-15 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the rejection is centered around the concept of undue experimentation, and the *In Re Wands* factors are cited in support thereof. Applicants traverse this rejection.

The *In re Wands* factors include:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The MPEP at 2164.01 provides further guidance:

> It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.
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> A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).
>
> The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a

conclusion reached by weighing all the above noted factual considerations. *In re Wands,* 858 F.2d at 737, 8 USPQ2d at 1404.

Although the Examiner asserts on page 7 of the Office Action that "Applicant has not provided any data suggesting that any molecule disclosed in the instant application would inhibit 11β-HSD-1," the instant case does provide disclosure of a SPA, and measurement of *in vivo* inhibition in the Examples.

Taken as a whole, the Wands factors do support Applicants' position that the claims are enabled. Specifically, the specification provides ample guidance and data covering specific compounds, which perform in the assays at physiological levels. The level of skill in the art is very high, as the artisan would be a highly trained medicinal chemist with experience in structure-activity relationships. The MPEP further states that:

> The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

MPEP, 2164.01

Based on the foregoing, Applicants assert the claims are enabled and in condition for allowance. If a telephonic communication will advance the prosecution of the instant application, please telephone Applicants' representative indicated below. Applicants believe no additional fees are due, but the Commissioner is authorized to charge any fees required in connection with this amendment to Merck Deposit Account No. 13-2755.

Respectfully submitted,

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